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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/708,881 | 03/30/2004 | Darrel Brodke | 101896-0244 | 2880 |
| 21125 | 7590 | 04/03/2008 | | |
| NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | EXAMINER RAMANA, ANURADHA | |
| | | | ART UNIT 3733 | PAPER NUMBER |
| | | | NOTIFICATION DATE 04/03/2008 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/708,881

Applicant(s)

BRODKE ET AL.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/30/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 9, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 1, the limitation "a thread depth remains constant along the length of the shank" is not supported by Applicant's disclosure because the thread depth is constant only in the proximal portion of the screw.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boucher et al. (US 5,443,509) in view of Ballintyn et al. (US 5,584,836), further in view of Rego, Jr. et al. (US 5,364,400).

Boucher et al. disclose a screw 101 including: a cylindrical shank 110; and radially symmetrical threads that are offset approximately 180 degrees from one another wherein a major diameter of the shank of the distal tip of the screw is equal to or less than the minor diameter of the proximal portion of the shank (Fig. 3, col. 5, lines 16-68 and col. 6, lines 1-5).

Boucher et al. disclose all elements of the claimed invention except for: a head; and relative dimensions of the distal and proximal portions of the screw; and the claimed ranges of length, pitch, thread width and minor diameter of the proximal portion of the screw (Fig. 2B and 3B).

Ballintyn et al. teach a screw made of a bioabsorbable material provided with a head having a recess for receiving an insertion tool to reduce shear stress and limit shear failure to the vicinity of the head of the screw (col. 1, lines 40-54).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Boucher et al. screw with a head, as taught by Ballintyn et al., to limit shear failure to only the head of the screw.

The combination of Boucher et al. and Ballintyn et al. discloses all elements of the claimed invention except for: (1) the distal portion of the shank having a length at least about 10% of the length of the bone screw; (2) the length of the screw to be in a range of about 20 mm to 100 mm with the distal portion of the shank having a length of about 10 mm; (3) a width of the thread crest to about 0.2 mm; and (4) the minor diameter of the proximal portion to be in a range of about 3 mm to 5 mm.

Rego et al. disclose typical interference screw dimensions of: length in a range of about 20 mm to 30 mm; thread pitch of about 0.11 inch (about 3 mm); a thread thickness or crest width of 0.013 inch (about 0.3 mm); a minor diameter of the proximal portion of the shank to be about 0.2 inch (about 5 mm); and a distal portion length that

Art Unit: 3733

is 28% of the length of the screw (col. 3, lines 28-33, col. 4, lines 38-68 and col. 5, lines 1-13).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have sized the screw of the combination of Boucher et al. and Ballintyn et al, as taught by Rego et al., for controllable insertion of the screw. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the screw of the combination of Boucher et al., Ballintyn et al. and Rego et al., with the claimed ranges of dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to have provided the claimed dimensions, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on January 9, 2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

Art Unit: 3733

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

March 31, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3733